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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

We REVERSE and ENTER A NEW GROUND UNDER 37 C.F.R. § 41.50(b).

29

- The Appellant invented a way to enable secure bioinformatics based 2transactions, in which on-line service is provided according to a voluntarily 3submitted genetic profile (Specification 3:3-9).
- An understanding of the invention can be derived from a reading of exemplary 5claim 1, which is reproduced below [bracketed matter and some paragraphing 6added].
- 7 1. Automated transaction method comprising the steps of: [1] determining electronically 8 a bioinformatic value associated with a user: and 9 [2] transacting via a processor with the user according to the 10 bioinformatic value. 11 12 wherein the bioinformatic value is automatically determined 13 when or after the user permits access to a voluntarilyselected portion of his or her personal genetic nucleotide 14 profile, 15 such accessible portion being 16 associated or 17 used with 18 19 evaluating the user transaction via said 20 processor, an other portion of such genetic profile being not 21 voluntarily-selected by the user and thereby inaccessible 22 23 for evaluating the user transaction. 24

This appeal arises from the Examiner's Final Rejection, mailed March 14, 262003. The Appellant filed an Appeal Brief in support of the appeal on June 19, 272003. An Examiner's Answer to the Appeal Brief was mailed on March 9, 2004. 28A Reply Brief was filed on May 10, 2004.

1

PRIOR ART

2 The Examiner relies upon the following prior art:

Beecham	US 5,876,926	Mar. 2, 1999
O'Flaherty	US 6,275,824 B1	Aug. 14, 2001
Hoffman	US 6,366,682 B1	Apr. 2, 2002
Rigault	US 6,389,428 B1	May 14, 2002

We also discuss the following art in this Decision:

Holden US 6,640,211 B1 Oct. 28, 2003

- 4 Asch, "Genetic Tests: Evolving Policy Questions," IEEE Technology and
- 5 Science Magazine, Winter 1996/1997, pp. 4-10 (1996).

6 REJECTIONS

- 7 Claims 1, 5, 7, 8, 11, 12, 21-25, and 27 stand rejected under 35 U.S.C. § 103(a) 8as unpatentable over Hoffman and O'Flaherty.
- 9 Claims 2-4, 6, 9, 10, and 28 stand rejected under 35 U.S.C. § 103(a) as 10unpatentable over Hoffman, O'Flaherty, and Beecham.
- Claim 26 stands rejected under 35 U.S.C. § 103(a) as unpatentable over 12Hoffman, O'Flaherty, Beecham, and Rigault.

1 ISSUES

- 2 The issues pertinent to this appeal are
- Whether the Appellant has sustained its burden of showing that the
- Examiner erred in rejecting claims 1, 5, 7, 8, 11, 12, 21-25, and 27 under
- 5 35 U.S.C. § 103(a) as unpatentable over Hoffman and O'Flaherty.
- Whether the Appellant has sustained its burden of showing that the
- Examiner erred in rejecting claims 2-4, 6, 9, 10, and 28 under 35 U.S.C.
- § 103(a) as unpatentable over Hoffman, O'Flaherty, and Beecham.
- Whether the Appellant has sustained its burden of showing that the
- Examiner erred in rejecting claim 26 under 35 U.S.C. § 103(a) as
- unpatentable over Hoffman, O'Flaherty, Beecham, and Rigault.
- The pertinent issue turns on whether it would have been obvious to use a 13personal genetic nucleotide profile as bioinformatics data in Hoffman.

FACTS PERTINENT TO THE ISSUES

- The following enumerated Findings of Fact (FF) are believed to be supported 3by a preponderance of the evidence.
- 4 Facts Related to Claim Construction
- 5 1. The disclosure contains no lexicographic definition of "transaction."
- 2. The ordinary and customary meaning of "transaction" is the act of
 transacting, i.e. conducting business.¹
- 8 Hoffman

3. Hoffman is directed to tokenless (i.e. without the use of a physical object, such as a credit card) authorization of commercial transactions between a buyer and a seller using a computer system. The buyer registers with the computer system a PIN, at least one registration biometric sample, and at least one buyer financial account. In a proposal step, a seller offers a proposed commercial transaction to the buyer. If the buyer accepts the seller's proposal, in an acceptance step, the buyer signals his/her acceptance by adding to the proposed commercial transaction the buyer's personal authentication information comprising a PIN and at least one bid biometric sample which is obtained from the buyer's person (Hoffman 4:18-33).

^{10&}lt;sup>1</sup> American Heritage Dictionary of the English Language (4th ed. 2000).

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1	4. Hoffman accepts biometric data electronically with a scanner. The
2	biometric scanner can be any one of fingerprint scanner, voice input
3	device (microphone), palm print scanner, retinal scanner or the like
4	(Hoffman 9:27-34).

- 5. Hoffman's biometric sample and PIN form personal authentication information in its transaction message (Hoffman 21:12-15).
- 7 O'Flaherty
- 6. O'Flaherty is directed to a database management system wherein the data in the database tables is controllably accessible according to privacy parameters stored in the database table. O'Flaherty stores privacy parameters collectively in database columns, and provides access to the data in the database table to a requesting entity solely in accordance with the personal privacy parameters (O'Flaherty 2:57 3:11).
 - 7. O'Flaherty masks data that is unauthorized (O'Flaherty 8:16-24).
- 15 Facts Related To The Level Of Skill In The Art
- 8. Neither the Examiner nor the Appellant has addressed the level of 16 ordinary skill in the pertinent arts of tracking items and data formatting. 17 18 We will therefore consider the cited prior art as representative of the level of ordinary skill in the art. See Okajima v. Bourdeau, 261 F.3d 19 1350, 1355 (Fed. Cir. 2001) ("[T]he absence of specific findings on the 20 level of skill in the art does not give rise to reversible error 'where the 21 prior art itself reflects an appropriate level and a need for testimony is 22 not shown") (quoting Litton Indus. Prods., Inc. v. Solid State Sys. Corp., 23 755 F.2d 158, 163 (Fed. Cir. 1985). 24

PRINCIPLES OF LAW

2Claim Construction

- During examination of a patent application, pending claims are given 4their broadest reasonable construction consistent with the specification. *In* 5re Prater, 415 F.2d 1393, 1404-05 (CCPA 1969); *In re Am. Acad. of Sci.* 6Tech Ctr., 367 F.3d 1359, 1364, (Fed. Cir. 2004).
- Limitations appearing in the specification but not recited in the claim are not 8read into the claim. *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. 9Cir. 2003) (claims must be interpreted "in view of the specification" without 10importing limitations from the specification into the claims unnecessarily).
- Although a patent applicant is entitled to be his or her own lexicographer of 12patent claim terms, in *ex parte* prosecution it must be within limits. *In re Corr*, 13347 F.2d 578, 580 (CCPA 1965). The applicant must do so by placing such 14definitions in the Specification with sufficient clarity to provide a person of 15ordinary skill in the art with clear and precise notice of the meaning that is to be 16construed. *See also In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) (although 17an inventor is free to define the specific terms used to describe the invention, this 18must be done with reasonable clarity, deliberateness, and precision; where an 19inventor chooses to give terms uncommon meanings, the inventor must set out any 20uncommon definition in some manner within the patent disclosure so as to give 21one of ordinary skill in the art notice of the change).

22 Obviousness

A claimed invention is unpatentable if the differences between it and the 24prior art are "such that the subject matter as a whole would have been obvious at 25the time the invention was made to a person having ordinary skill in the art."

- 135 U.S.C. § 103(a) (2000); KSR Int'l v. Teleflex Inc., 127 S.Ct. 1727 (2007); 2Graham v. John Deere Co., 383 U.S. 1, 13-14 (1966).
- In *Graham*, the Court held that the obviousness analysis is bottomed on 4several basic factual inquiries: "[(1)] the scope and content of the prior art are to be 5determined; [(2)] differences between the prior art and the claims at issue are to be 6ascertained; and [(3)] the level of ordinary skill in the pertinent art resolved." 383 7U.S. at 17. *See also KSR Int'l v. Teleflex Inc.*, 127 S.Ct. at 1734. "The 8combination of familiar elements according to known methods is likely to be 9obvious when it does no more than yield predictable results." *KSR*, 127 S.Ct. at 101739.
- "When a work is available in one field of endeavor, design incentives and 120ther market forces can prompt variations of it, either in the same field or in a 13different one. If a person of ordinary skill in the art can implement a predictable 14variation, § 103 likely bars its patentability." *Id.* at 1740.
- 15 "For the same reason, if a technique has been used to improve one device, 16and a person of ordinary skill in the art would recognize that it would improve 17similar devices in the same way, using the technique is obvious unless its actual 18application is beyond his or her skill." *Id*.
- "Under the correct analysis, any need or problem known in the field of 20endeavor at the time of invention and addressed by the patent can provide a reason 21for combining the elements in the manner claimed." *Id.* at 1742.

1 ANALYSIS

- 2 Claims 1, 5, 7, 8, 11, 12, 21-25, and 27 rejected under 35 U.S.C. § 103(a) as 3 unpatentable over Hoffman and O'Flaherty.
- 4 The Appellant argue these claims as a group.
- Accordingly, we select claim 1 as representative of the group. 637 C.F.R. § 41.37(c)(1)(vii) (2007).
- The Examiner found that Hoffman described all the limitations of claim 1 8except for a personal genetic nucleotide profile and having a selectable portion be 9voluntarily accessible and another portion inaccessible. The Examiner found that a 10nucleotide profile was simply a long PIN (personal identification number) and that 11O'Flaherty described a system allowing a user to selectively make portions of data 12accessible. (Answer 4-5).
- The Appellant contends that Hoffman provides no suggestion for using a 14personal genetic nucleotide profile (Br. 9) and further, that in the absence of such a 15suggestion, there would be no reason to apply O'Flaherty (Br. 12).
- The Examiner responded by taking official notice that a personal genetic 17nucleotide profile is biometric data and Hoffman accesses biometric data (Answer 1821:Top ¶). The Examiner cites several additional references as evidence that a 19nucleotide profile may be biometric data in support. The Appellant in turn 20responds that these references are not of record and more critically, do not suggest 21the use of such nucleotide data for transactions (Reply Br. 2:First and second full 22¶'s).
- We agree. While the Examiner is correct that Hoffman accepts bioinformatic 24data for transactions (FF), Hoffman relies upon a scanner that measures 25observable physical characteristics, such as fingerprints, voice prints, palm prints,

1 and retinal patterns (FF). While it is undoubtedly true that a personal genetic 2 nucleotide profile is biometric data, this alone is insufficient to find that Hoffman 3 would have used such a profile, since a scanner as described by Hoffman could not 4 obtain a genetic nucleotide profile.

- 5 This is hardly surprising, because Hoffman is clearly directed to authentication 60f a user, not analyzing a user's genetic DNA. Hoffman uses its biometric sample 7 and PIN to form personal authentication information in its transaction message (FF 8). Thus, Hoffman acquires biometric information that identifies who is actually at 9the scanning device to ensure that person is properly authenticated. Claim 1 recites 10the limitation of relying on a nucleotide profile to complete a transaction. There is 11no requirement that the profile be from a person presently at an input device, nor 12any requirement for authenticating that the profile actually is the user's, although 13the claim requires that the profile actually be the user's. There is simply no way 14for Hoffman's scanner to produce such a profile, and such a profile would be 15useless to Hoffman's authentication mechanism. Thus, we find the Examiner erred 16in rejecting claim 1 over Hoffman and O'Flaherty. Since independent claim 27 17 and the remaining dependent claims incorporate this limitation of a personal 18genetic nucleotide profile, we find the Examiner has similarly erred in rejecting 19those claims.
- The Appellant has sustained its burden of showing that the Examiner erred in 21rejecting claims 1, 5, 7, 8, 11, 12, 21-25, and 27 under 35 U.S.C. § 103(a) as 22unpatentable over Hoffman and O'Flaherty.

- 1 Claims 2-4, 6, 9, 10, and 28 rejected under 35 U.S.C. § 103(a) as unpatentable 2 over Hoffman, O'Flaherty, and Beecham.
- These claims similarly incorporate the limitation of a personal genetic 4nucleotide profile, and we find the Examiner has erred in rejecting these claims for 5the same reasons we cited, *supra*.
- The Appellant has sustained its burden of showing that the Examiner erred in 7rejecting claims 2-4, 6, 9, 10, and 28 under 35 U.S.C. § 103(a) as unpatentable 8over Hoffman, O'Flaherty, and Beecham.
- 9 Claim 26 rejected under 35 U.S.C. § 103(a) as unpatentable over Hoffman, 10 O'Flaherty, Beecham, and Rigault.
- This claim similarly incorporates the limitation of a personal genetic nucleotide 12profile, and we find the Examiner has erred in rejecting this claim for the same 13reasons we cited, *supra*.
- The Appellant has sustained its burden of showing that the Examiner erred in 15rejecting claim 26 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, 16O'Flaherty, Beecham, and Rigault.

17 CONCLUSIONS OF LAW

The Appellant has sustained its burden of showing that the Examiner erred in 19rejecting claims 1-12 and 21-28 under 35 U.S.C. § 103(a) as unpatentable over the 20cited prior art.

NEW GROUND OF REJECTION

- The following new grounds of rejection are entered pursuant to 337 C.F.R. § 41.50(b).
- Independent claims 1, 27, and 28 are rejected under 35 U.S.C. § 102(e) as 5anticipated by Holden. Dependent claims 10-12, 21, and 23-26 are rejected under 635 U.S.C. § 103(a) as unpatentable over Holden. Claims 2-4, 6-9, and 22 are 7rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and Asch. Claim 5 8is rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and O'Flaherty.

9 ADDITIONAL FACTS PERTINENT TO THE ISSUES

The following additional enumerated Findings of Fact (FF) are believed to be 11supported by a preponderance of the evidence.

12 Holden

- 9. Holden is directed to storing and accessing genetic information and providing protection against unauthorized access and use, but providing convenience in accessing and using genetic information if such use is properly authorized (Holden 1:23-27).
 - 10. Holden's patient enrolls in a genetic banking system for multiple patients and provides a source of genetic material, such as a blood sample. The sample is processed to produce a genetic profile for the patient. The processed data is stored in a database to create a genetic profile for that patient (Holden 1:28-35).
- 11. The patient, either at the time of enrollment or after a sample is processed, can dictate access rights, including the ability of third parties (other than the individual or the genetic bank itself), such as medical

1	practitioners, to access this profile, and the specific purposes for which
2	the profile can be accessed and used. Thus, the patient can specify both
3	the people who will have access, and the uses for which they have access
4	(Holden 1:36-43).
5	12.A medical practitioner authorized to have access by the patient and
6	confirmed by the access control system can access the profile and
7	perform a transaction such as running tests based on the profile (Holden
8	1:49-54).
9	13. Holden's system allows users to store a comprehensive digitized DNA
10	profile based on a sample. The patient has control to voluntarily allow
11	access to particular people and for particular purposes, thus protecting
12	the privacy of that information (Holden 1:63-67).
13	14. Holden's system may include data integration and analysis
14	functionalities (Holden 2:19-21).
15	15. Holden describes the use of a server in a separate system for data access
16	(Holden 2:39-48).
17	16. Some of Holden's authorized third parties may have access for some
18	purposes and not for other purposes (Holden 2:60-65).
19	17. Holden derives its profiles by the genetic banking and testing services
20	that are provided, and can include genotyping and bioinformatic
21	profiling of general and/or specific genetic marker panels. Such
22	information can be used to determine risks of many diseases including,
23	without limitation, cancer, Huntington's Disease, Alzheimer's Disease,
24	and hypertension. The data that is provided from these tests is digitally

- stored in the database as a genetic profile of the patient for subsequent analysis and tests (Holden 3:31-47).
 - 18.If access is allowed, Holden's practitioner can seek to have a test performed, such as a search of the profile for markers for Huntington's Disease. The system determines whether the test is authorized by comparing the type of test that is desired with the access rights entered by the patient (a practitioner may have access for some purposes but not others). If the test is authorized, the processing system forwards the request to the testing system to perform the test (Holden 3:66 4:6).
 - 19.Holden's system allows a patient to voluntarily bank genetic information that can be used quickly to determine genetic and medical information about that individual, particularly information that relates to whether the individual carries genetic information associated with known diseases. The system provides restrictions, however, that allow the user to retain privacy and limit unauthorized access to his/her genetic information. The system is thus unlike a system, for example, in which DNA information, like fingerprint information, is stored for identification purposes to use DNA information to identify individuals involved in specific criminal activities; in such a case, the individual who provides the sample would generally not have voluntary control to establish the ability of others to access the information, and such systems would generally not have the ability to test for a number of different medical purposes for which the DNA information can be accessed by others (Holden 5:62 6:12).

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Asch

20. Asch is directed to exploring policy questions surrounding genetic testing (Asch 4:Title).

21.A 1991 survey of insurers found that most health insurers believe it is fair for insurers to use genetic tests to identify individuals with increased risk of disease, and that they should have the option of determining how to use genetic information in determining risks. One reason insurers might use such tests is that individuals can undergo genetic testing on their own, and if they discover that they are at greater medical risk they might purchase more insurance. This phenomenon, known as adverse selection, puts insurance companies at a disadvantage if they lack access to the same information. To level the playing field, insurance companies might have a legitimate interest in the results of genetic tests already performed, and might have an incentive to initiate testing for selected conditions. When one insurer begins to use genetic information in its risk rating, others must follow or they will disproportionately attract individuals who are denied coverage elsewhere. This suggests that insurance companies will inevitably begin to use genetic information in risk rating, despite the expense and complexities involved. Some analysts have argued that this inexorable trend contradicts the rationale for insurance in the first place (Asch 9:Left col. Third full ¶ - Right col. First full ¶).

1 ANALYSIS

The anticipation of claims 1, 27, and 28 by Holden is demonstrated in the 3following chart.

Claim 1	<u>Holden</u>
1. Automated transaction method	
comprising the steps of:	
[1] determining electronically a	Running tests based on the stored
bioinformatic value associated with a	profile (Holden 1:49-54)
user; and	
[2] transacting via a processor with the	Same as above - basing on profile
user according to the bioinformatic value,	shows the determination, running
wherein the bioinformatic value is	tests shows the transaction
automatically determined	
when or after the user permits access to a	Patient voluntarily allows access
voluntarily-selected portion of his or her	for particular people and purposes
personal genetic nucleotide profile,	(Holden 1:63-67) genotyping
	and bioinformatic profiling of
	genetic marker panel (Holden
	3:34-39); nucleotide
	polymorphism map (Holden 4:38-42)
such accessible portion being associated	Running tests based on the stored
or used with evaluating the user	profile (Holden 1:49-54)
transaction via said processor,	
an other portion of such genetic profile	A practitioner may access for
being not voluntarily-selected by the user	some purposes but not others
and thereby inaccessible for evaluating	(Holden 4:1-5)
the user transaction.	
The party processing the transaction	The party is a medical practitioner
being a caregiver (Claim 28)	(Holden 1:36-43)

All of the limitations of claims 27 and 28 form a subset of the limitations of 5claim 1, except the claim 28 limitation of a caregiver, which is also included in the 6chart.

- 1 As to claims 10-12, 21, and 23-26, rejected as obvious over Holden, we find as 2follows.
- Holden describes a server for storing data and remote transactions (FF)
- 4 (claim 10).
- A portable computer is a predictable variation of Holden's computer and
- 6 patient control over data implies a patient identification, which is sufficient
- 7 to create a patient account (claim 12).
- 8 Holden describes multiple patients (FF) (claim 11).
- Holden describes a remote system (FF), which implies origination and
- transmission of a data as a signal (claims 21 and 25).
- Holden describes data analysis functionality (FF). Analysis testing for data
- that is clearly incorrect (claim 23) or comparing differences between similar
- data (claim 24) are known by those in the art of data analysis to be
- predictable variations of data analysis in general, and indeed are frequently
- 15 considered "sanity check" type testing to determine anomalies. The
- 16 combination of familiar elements according to known methods is likely to be
- obvious when it does no more than yield predictable results. KSR, 127 S. Ct.
- 18 at 1739.
- The DNA profiles of Holden clearly have correspondence with at least a
- single nucleotide polymorphism (claim 26).

- 1 As to claims 2-4, 6-9, and 22, rejected over Holden and Asch, we find as 2follows.
- Asch describes the use of genetic profile information as requisites for
- 4 insurance policies (FF). Claim 2 requires such an insurance policy, and
- claims 3 and 4 require a service contract or bid to serve, each of which a
- 6 health insurance policy would represent.
- 7 Asch describes the lack of precision in predicting actual circumstances,
- 8 implying the actuarial table of claim 6, and the applicability to group
- 9 insurance and the policy questions regarding discrimination, implying the
- non-discrimination of claim 7.
- Claims 8 and 9 recite multiple values from the bioinformatic data, which the
- various tests described by Holden would require, and such data also
- indicating a change in risk, which Holden's examples describe.
- Claim 22 requires competitive transactions and insurance transactions are
- 15 known to be competitive.
- One of ordinary skill would have considered the transactional considerations
- of Asch after considering Holden because of Asch's description of the
- commercial policy implications of the technology employed by Holden, and
- found it obvious to combine their teachings.
- As to claim 5, rejected over Holden and O'Flaherty, O'Flaherty describes the 21use of masking to accomplish data hiding (FF &). One of ordinary skill would 22have seen this as an implementation technique for Holden's denial of access to 23some portions of data (FF) and found it obvious combine them by employing 24O'Flaherty for its implementation details.

2	To summarize, our decision is as follows:
3	• The rejection of claims 1, 5, 7, 8, 11, 12, 21-25, and 27 under 35 U.S.C. § 103(a) as unpatentable over Hoffman and O'Flaherty is not sustained.
5 6	• The rejection of claims 2-4, 6, 9, 10, and 28 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, O'Flaherty, and Beecham is not sustained.
7 8	• The rejection of claim 26 under 35 U.S.C. § 103(a) as unpatentable over Hoffman, O'Flaherty, Beecham, and Rigault is not sustained.
9 10	• The following new grounds of rejection are entered pursuant to 37 C.F.R. § 41.50(b).
11 12	 Independent claims 1, 27, and 28 are rejected under 35 U.S.C. § 102(e) as anticipated by Holden.
13 14	 Claims 10-12, 21, and 23-26 are rejected under 35 U.S.C. § 103(a) as unpatentable over Holden.
15 16	 Claims 2-4, 6-9, and 22 are rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and Asch.
17 18	 Claim 5 is rejected under 35 U.S.C. § 103(a) as unpatentable over Holden and O'Flaherty.
19 20m	No time period for taking any subsequent action in connection with this appearage as the extended under 37 C.F.R. § 1.136(a)(1)(iv).
21	<u>REVERSED</u>
22 23	<u>41.50(b)</u>

DECISION

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